

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT(S):** Parikh et al.                      **CONFIRMATION No.:** 7862  
**APPLICATION No:** 09/443,863                      **EXAMINER:** Gollamudi S. Kishore  
**FILING DATE:** November 19, 1999                      **ART UNIT:** 1612  
**FOR:** DISPERSIBLE PHOSPHOLIPID STABILIZED MICROPARTICLES

**Mail Stop AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 CFR § 1.132 OF INDU PARIKH**

I, Indu Parikh of 2558 Booker Creek Rd, Chapel Hill, NC 27514, declare and state:

1. I have read and understand the subject matter described and claimed in the instant application, United States Patent Application Serial No. 09/443,863 filed November 19, 1999 ("the '863 application"), entitled "Dispersible Phospholipid Stabilized Microparticles".

2. I have read and understand the final Office Action mailed of August 28, 2008 and understand that claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under 35 U.S.C. §103(a) as being unpatentable over WO 98/07414 ("the '414 publication") in view of US Patent No. 5,976,577 ("Green") or US Patent No. 6,475,510 ("Venkatesh").

3. I am a co-inventor of the '863 application.


4. I am an author of the '414 publication, entitled "Compositions Comprising Microparticles of Water-insoluble Substances and Method for Preparing Same" cited in the instant 103(a) rejection.

5. I make this Declaration to establish that what I invented in the '414 publication includes a process of preparing rapidly dispersing oral dosage forms of hydrophobic compounds

wherein the particles are coated with at least two surfactants; wherein one of the surfactants was a phospholipid (surface modifying agent). The average particle sizes of the hydrophobic compound were less than 10 microns. The composition contained other materials such as cellulose and mannitol. The process of preparation involved mixing of the components (water insoluble active agent and the surface modifying agents) in an aqueous medium, sonicating it and lyophilizing the composition to form particles. The lyophilized powders could be converted into granules or tablets with the addition of binders and other excipients.

6. I assert that the other inventors did not work on the portions of the '414 publication discussed in point 5.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

  
Indu Parikh

12-24-08  
Date